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In Re: Patent Term Extension
Applications for
U.S. Patent No. 5,260,273 and
U.S. Patent No. 5,789,381

**DECISION DENYING APPLICATIONS FOR PATENT TERM
EXTENSION FOR U.S. PATENT NOS. 5,260,273 AND 5,789,381**

This is in response to the applications for interim patent term extension of the term of U.S. Patent No. 5,260,273 (the '273 patent) and U.S. Patent No. 5,789,381 (the '381 patent) under 35 U.S.C. § 156, filed in the United States Patent and Trademark Office (USPTO) on October 6, 2009. The application was filed by Discovery Laboratories Inc. on behalf of the patent owner, Scripps Research Institute (Applicant). Extension is sought based upon the continuing premarket review under § 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) of the human drug product known as SURFAXIN® (lucinactant) by the Food and Drug Administration (FDA). Because the patent term extension statute only contemplates granting a certificate of extension of a single patent for a single regulatory review period, the present applications for interim patent term extension for the '273 patent and the '381 patent must be **DENIED** in favor of the grant of interim extension in the provisionally elected patent for which interim extension is granted, U.S. Patent No. 5,407,914.

DECISION

Applicant points out in their applications for patent term extension that the provision in § 156(c)(4) clearly prohibits extension of more than one patent for a single regulatory review period under § 156(e)(1), but that there is no explicit prohibition against multiple interim patent term extensions under § 156(d)(5). Although this statement is *per se* true, the statement fails to consider the statutory language as a whole, the USPTO's long-standing practice and public interest.

I. Statutory Construction Requires Looking at the Statute as a Whole

"The starting point in every case involving construction of a statute is the language itself." *Santa Fe Indus., Inc. v. Green*, 430 U.S. 462, 472 (1977). When construing language in a statute, the terms must be construed "in accordance with [their] ordinary or natural meaning." *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 449 (2007). Applicant would have the USPTO focus solely on the provision of § 156(c)(4) which explicitly states, "in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period." That focus fails to give meaning to all the statutory provisions. The Court has spoken on this issue and stated, "[w]e must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 99 (1992); *see also*

Splane v. West, 216 F.3d 1058, 1068 (Fed. Cir. 2000) (“We must construe a statute ... to give effect and meaning to all its terms.”). Moreover, the Federal Circuit has concluded “[i]f the statutory language is clear and unambiguous, the inquiry ends with the plain meaning.” *Myore v. Nicholson*, 489 F.3d 1207, 1211 (Fed. Cir. 2007).

The explicit language of section 156, in many instances, states that it is the term of “a patent” which shall be extended. Additionally, the statute provides for “an extension of the term of a patent.” See § 156(d)(1). This is not the first time that the USPTO has been required to interpret the language “a patent.” It is a long-standing interpretation of the USPTO that “a patent” means one patent. In the context of double patenting, the USPTO’s Manual of Patent Examining Procedure (MPEP) clearly explains a “‘same invention’ type double patenting rejection [is] based on 35 U.S.C. 101 which states in the singular that an inventor ‘may obtain a patent.’” See MPEP 804 (emphasis added).

The tenants of statutory construction require consideration of the statutory scheme as a whole, giving terms their plain and ordinary meaning. The dictionary definition of “a,” as an indefinite article, is “used before nouns and noun phrases that denote a single but unspecified person or thing.”¹ Similarly, the use of “an,” as an indefinite article, is defined as the “form of ‘a’ used before words with a vowel or with an unpronounced h.”² The following table summarizes some sections of the statutory language of section 156 which limit extension to “a” patent.

Section	Language
156(a)	[t]he term of <u>a</u> patent which claims a product. . . . shall be extended. . . .
156(b)(1)	in the case of <u>a</u> patent which claims a product, be limited to
156(b)(2)	in the case of <u>a</u> patent which claims a method of using a product, be limited to
156(b)(3)	in the case of <u>a</u> patent which claims a method of manufacturing a product, be limited to
156(d)(1)	To obtain <u>an</u> extension of the term of a patent under this section. . . .
156(d)(5)(C)	The owner of record of <u>a</u> patent, or its agent, for which <u>an</u> interim extension has been granted under subparagraph(b),

¹ See definition for “a” as an indefinite article at: <http://www.thefreedictionary.com/a>

² See definition for “an” as an indefinite article at: <http://www.thefreedictionary.com/an>

Based on the language of the statute, as a whole, and the plain meaning of “a patent,” the statute only contemplated that a single patent is entitled to have the term extended for the same (single) regulatory review period. Similarly, the explicit language of section 156(d)(5)(C) makes clear that interim extension is applicable only for “a patent,” stating, “[t]he owner of record of a patent, or its agent, for which an interim extension has been granted under subparagraph (b), may apply for not more than 4 subsequent interim extensions under this paragraph. . . .” The plain language of obtaining “an extension” for “a patent” delineates that the patent term extension statute contemplates that only one patent may be granted an interim extension. Furthermore, the language of § 156 distinguishes “interim extension” from “extension” by referring throughout subsection 156(d)(5) that the extension is “an interim extension.” See e.g., § 156(d)(5)(F) indicating that the rights derived are “during the period of interim extension.” (emphasis added).

II. Long-Standing Practice

In the approximately 25 years since the enactment of the Hatch-Waxman Act where the USPTO has been administering 35 U.S.C. § 156, the USPTO has not granted multiple interim patent term extensions under 35 U.S.C. § 156(d)(5) for a same (single) regulatory review period. Thus, it would be contrary to long-standing USPTO practice to do so now.

III. Grant Of Multiple § 156(d)(5) Extensions Would Ultimately Amount To Improvident Grant Of Term Extensions In Patents Which Were Not Entitled To Receive Extension

Because the statute does not prohibit a patent owner from seeking extension on more than one patent, an applicant may apply for extension of multiple patents. See 37 C.F.R. § 1.785. In that case, the USPTO and the regulating agency concurrently process the multiple applications for patent term extension and require election of a single patent to receive the certificate of extension under 35 U.S.C. § 156(e)(1). When there is no imminent expiration of a patent for which a certificate of extension is being sought, no interim extension is granted. Thus, at the conclusion of processing of multiple applications for patent term extension based on a same (single) regulatory review period, the elected patent would receive a certificate of extension and the non-elected patents would expire on their original expiration dates. However, unlike here, where the original expiration of the patent(s) are imminent, the USPTO has no authority to grant multiple interim extension under § 156(d)(5) to patent(s) which will not ultimately receive a certificate of extension. Any interim patent term extensions granted to patents which are ultimately not elected is tantamount to granting additional patent rights where the statute does not authorize the USPTO to so grant.

IV. Granting Interim Extension To A Single Patent When Only One Can Ultimately Be Extended Ensures The Public Of The Patent Rights Associated With The Product

Upon approval of the subject product, SURFAXIN®, the FDA would publish in the Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) the patent numbers of patents, which claim the product, SURFAXIN®, or a

method of using the product, SURFAXIN®, along with their respective expiration dates. Any member of the public desiring to determine when the patent protection ends for SURFAXIN® would see patents listed with expiration dates relating to the grant of multiple interim extensions. That situation would lead to confusion, since ultimately only one certificate of extension will be granted. Providing certainty for the public is ensured by granting an interim patent term extension only where warranted, here, that means that only the provisionally elected '914 obtains interim patent term extension.

V. Granting multiple interim extensions would permit additional patents to be listed in the FDA's Orange Book

When a New Drug Application (NDA) is filed with FDA, the marketing applicant must submit to FDA patent information. Specifically, the NDA contains information relating to patents which are alleged to claim the drug product or a method of using the drug product. Upon approval of the drug product, such patents would be automatically listed by FDA, provided that the patents have not expired. The ability of the patent owner (the marketing applicant before the FDA) to list additional patents in the FDA's Orange Book would require additional patent certifications for any filers of applications for drug approval under § 505(j) and § 505(b)(2) of the FFDCA. In granting multiple interim extensions, as sought in this case, means the additional patents would be listed in the Orange Book, necessitating additional patent certifications, and potentially leading to additional litigation. Such unnecessary litigation over patent(s) which would, ultimately, not receive a certificate of extension would nonetheless be required to resolve any patent certifications submitted by an abbreviated new drug application filer indicating non-infringement or invalidity of any listed patent. In granting a single interim extension under 35 U.S.C. § 156(d)(5) any abbreviated new drug application filer would be required to provide patent certifications for only the patent which would ultimately be eligible for a certificate of extension.

CONCLUSION

Applicant's PTE applications for U.S. Patent Nos. 5,260,273 and 5,789,381 are **DENIED**.

This is considered final agency action.

Any correspondence with respect to this matter should be addressed as follows:

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RE: SURFAXIN®
Docket No.:

Attention: Beverly Friedman